

**Appl. No.** : 09/981,783  
**Filed** : October 17, 2001

### **REMARKS**

The amendments herewith and Applicants' remarks are responsive to the Office Action dated December 9, 2003 in the subject application.

Claim 1 is amended to more clearly recite the structure of the microporous fibers based on the specific language of the application found in paragraph 2 on page 2 of the application. In addition, the term "zone" has been deleted, the term being unnecessary to the description of the fiber wall structure recited in the claim. The claim is also amended to recite that the fibers are capable of separating plasma from whole blood by passing the plasma through the fiber wall from the outer wall surface to the inner wall surface and interior lumen based on the description of the function of the fiber for separating blood plasma from blood as disclosed throughout the application, for example in paragraphs 2, 11 and 15 of the specification. Claim 2 is amended to include the additional recitation of the elongated hollow tubes referring to the first of such tubes. Claims 30, 31 and 32 are amended to delete the unnecessary term "membrane" referring to the fiber wall. The amended claims are dependant on Claim 1 which does not recite the antecedent term which has been deleted from the claims. Claims 43 and 44 are amended to delete the dependency on Claim 15, thereby obviating the rejection of improper multiple claim dependency. Claim 43 is also amended to add the term "wall", referring to the outer wall surfaces of the fiber. The amendments to the claims are fully supported by the original specification and do not include new matter.

Claim 1 has been rejected under 35 U.S.C. § 112 due to a lack of antecedent basis for the fiber wall. It is submitted that the amendment of the language of the claim obviates the rejection.

Claim 2 is rejected for reciting "one or more first hollow tubes" which is stated to be already recited in Claim 1. The rejection is improper since Claim 1 does not recite the first or second elongated hollow tubes, but instead recites "one or more elongated hollow tubes". Thus, the language of Claim 2 reciting one or more first elongated hollow tubes and one or more second elongated hollow tubes is not indefinite nor is it redundant of the language of Claim 1. The Examiner states that similar problems exist with Claim 3 and two hollow tubes as well as Claims 8 and Claim 9. The rejection is not understood. Claim 3 is dependent on Claim 2 which recites two of said elongated hollow tubes. Claim 2 recites one or more first elongated hollow tubes and one or more second elongated hollow tubes, whereby it is submitted that the dependent Claim 3 is not indefinite for the reasons set forth by the Examiner. Similarly, Claim 8 recites

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first and second fibers which are distinguished from the fibers of Claim 7 on which Claim 8 is dependent. It is submitted that the language of Claim 9 is not indefinite regarding the first and the second hollow tubes recited which are fully supported by the antecedent basis of the language of Claim 2 on which Claim 9 is ultimately dependent. Accordingly, it is submitted that the rejections of Claims 1, 2, 3, 8 and 9 under 35 U.S.C. § 112, second paragraph, are improper. If the Examiner persists in repeating rejection of one or more of those claims, it is specifically requested that the specific language purported to be indefinite be pointed out and an explanation of what is indefinite be given.

Claims 1 and 30-41 are rejected under 35 U.S.C. § 103 (a) as unpatentable over Gorsuch '809 in view of Oishi (EP '494). The rejection is respectfully traversed. Gorsuch is directed to a fiber assembly capable of *in-vivo* plasma separation describing a filter element having elongated hollow microporous fiber loops extending from a catheter surface. The Examiner recognizes that the fibers disclosed by Gorsuch do not meet the asymmetrical fiber wall morphology of the fibers recited in the filter device of Claim 1. In both the Gorsuch filter as well as the filter recited in Claim 1, filtration and separation of plasma from whole blood is carried out by directing plasma through the fiber wall from the outer fiber surface to the inner fiber surface. Gorsuch discusses the flow of plasma through the pores of the hollow fibers from the exterior fiber to the interior, for example, in Col. 1, line 5-20, as well as U.S. patent No. 5,224,926, incorporated into Gorsuch '809 by reference. Thus, the filters of Gorsuch and that recited in the present application are implanted in the blood vessel of a patient for separating the plasma from the blood which flows along the outer surface of the fiber and the plasma passing from the outer wall surface to the inner fiber lumen.

The Examiner combines the teaching of Oishi with Gorsuch to substitute the Oishi fibers for those of Gorsuch. The combination of references is alleged to meet Applicants' filter devices under 35 U.S.C. § 103. It is submitted that the combination of references is improper under 35 U.S.C. § 103. Moreover, it is submitted that even if the references are combined, Applicants' claimed filter is not taught or suggested.

Again referring to Applicants' Claim 1, the filter device recites fibers which are capable of separating plasma from whole blood by passing the plasma through the fiber wall from the outer wall surface to the inner wall surface and interior lumen of the fiber. As discussed above, the Gorsuch fiber also separates the plasma by passing it through the fiber from the outer wall to

the inner wall. However, Oishi does not filter by passing fluid or filtrate from the outer wall fiber surface to the inner lumen of the fiber. Instead, Oishi filters from the inner surface of the fiber to the outer surface, exactly opposite from that of either Gorsuch or Applicants' fiber (see page 5, lines 1-3). Indeed, the specific effective membrane area of the Oishi fiber is discussed in terms of the inner surface through which the fluid to be treated is directed and through which the filtrate first passes. Moreover, the Oishi fibers are disclosed for the purpose of removing muddiness in tap water and processing water in the fields of fermentation and food or for treating water in nuclear power stations or thermal power stations, see page 7, lines 36-38. There is no suggestion or teaching whatever of using the Oishi fibers for separating plasma from blood, let alone for being inserted into the blood vessel of a patient for separating plasma.

It is well understood that for a proper combination of references under 35 U.S.C. § 103, there must be a teaching, suggestion, or motivation to combine the references; see *In re Rouffet*, 47 U.S.P.Q.2<sup>nd</sup> 1453; *In re Fritch*, 23 U.S.P.Q.2<sup>nd</sup> 1780; *In re Fine*, 5 U.S.P.Q.2<sup>nd</sup> 1596. It is submitted that there is no motivation whatever for substituting a fiber membrane used for filtering muddy water or other industrial use by filtering from the inner lumen of the fiber the outside of the fiber, i.e., passing the filtrate from the inner lumen to the outer surface of the fiber for the Gorsuch fibers which filter from the outer fiber surface to the inner fiber lumen. Indeed, such a combination for the proposed rejection of Applicants' claims is simply illogical. If the Examiner persists in repeating the rejection based on the combination of Gorsuch with Oishi, it is requested that motivation for combining the references be specifically pointed out.

It is submitted that even if the references are combined, there is no teaching or suggestion of Applicants' claimed filter device. Assuming, for arguments sake, the references are combined as proposed by the Examiner, the resulting fiber used in the Gorsuch plasma extraction device would be the Oishi fibers. The Oishi fibers are characterized by requiring a critical "inner thick trunk" structure having a specific maximum diameter of 10-30  $\mu\text{m}$  as discussed on page 3, lines 18-25 of the reference. The Oishi fibers then filter by passing filtrate from the thick trunk inner surface to the smaller pore outer surface; again, see page 5, lines 1-3. Thus, the resulting fiber from the Examiner's combination is a filter to be implanted in a blood vessel having an inner fiber wall characterized by critical thick trunks through which the filtrate passes from the inner fiber lumen to the outside of the fiber. How would blood be directed into the interior fiber lumen? How would separated plasma be recovered by the filter? How would such a filter device

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be used in separating plasma from blood within a patient blood vessel? It is submitted that the filter resulting from the combination references does not meet Applicants' filter device for separating blood plasma from whole blood within a blood vessel by passing the plasma filtrate through the fiber wall from the outer wall surface to the inner wall surface and inner fiber lumen as is recited in Applicants' claims. Accordingly, it is submitted that the rejection of Applicants' claims by the combination of references is improper under 35 U.S.C. § 103 and should be withdrawn.

For the forgoing reasons, it is submitted that the claims are patentable over the combined prior art, and that the case is in condition for allowance. Accordingly, notification thereof is respectfully requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 2/25/04

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